JAN 13 2006 K052741

510(k) SUMMARY

Submitted by: W & H Dentalwerk Buermoos GmbH
Ignaz-Glaser-Strasse 53
A - 5111 Buermoos
Austria

Contact person: Gabriele Wienbeck
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Date of Preparation: 15/08/2005

Device name: implantMED SI-915/923

Common Name: Surgical motor unit for implantology and maxillo surgery

Classification Name: Controller, foot, handpiece and cord

Predicate device: implantMED (K002469)

Device Description:

The implantMED SI-915/923 consist of a small hand held motor, a foot control and a controller. Accessories complete the device. They are designed for use in dental surgery.

Optimum irrigation of the treatment site is an important factor for successful treatment. An integrated pump is used to supply the treatment fluid / coolant from its reservoir via a pump to the motor / handpiece.

Intended use:

Mechanical drive unit with coolant supply for transmission instruments with coupling system according to ISO 3964.

The equipment is a drive unit for use in dental surgery, implantology, maxillo-facial surgery and endodontics for treatment of dental hard tissue and mechanical rotating root canal preparation.

Technological Characteristics:

The "implantMED SI-915/923" is the update of the previous version. The technological characteristics are very similar to the old device.

Substantial equivalence:

The updated and the predicate device share the same indication for use. Comparisons of the subject and the previous version show similar technological characteristics, performance properties and biocompatibility.

The "implantMED SI-915/923" is substantially equivalent to the device it was modified from, the "implantMED SI-95"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

Ms. Gabriele Wienbeck
Regulatory Affairs
W&H Dentalwerk Buermoos GmbH
Ignaz-Glaser Strasse 53
A-5111 Büermoos
AUSTRIA

Re: K052741
Trade/Device Name: ImplantMED SI-915 (115V Version) ImplantMED SI-923 (230V Version) Incl. Accessories
Regulation Number: 872.4200
Regulation Name: dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: December 16, 2005
Received: December 16, 2005

Dear Ms. Wienbeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

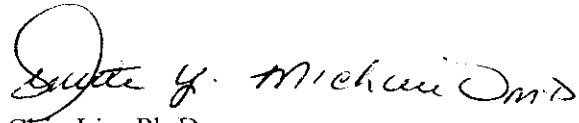
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) (if known): K052741

Device Name: implantMED SI-915 (115V version)
implantMED SI-923 (230V version)
incl. accessories

Indication for Use:

Mechanical drive unit with coolant supply for transmission instruments with coupling system according to ISO 3964. The equipment is a drive unit for use in dental surgery, implantology, maxillo-facial surgery and endodontics for treatment of dental hard tissue and mechanical rotating root canal preparation

Prescription Use X AND/OR Over- The –Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices, Office of Device Evaluation
510(k) Number K052741